

**Genetically Modified Salmon Controversies in the United States:
Does the Current Regulatory Paradigm Address all the Issues?**

By

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Abstract

If approved by the Food and Drug Administration (FDA), the genetically modified salmon will be the first genetically engineered animal available for human consumption in the United States. The country relies on the Food and Drug Administration and other federal and state agencies to develop policies that consider unbiased evidence and expert policy development in the evaluation of food products.

I propose that the current information available regarding the acceptance of genetically modified salmon as a human food is not yet adequate for approval, as evidenced by the number of related public health issues that still remain unresolved.

A thorough review of the literature with a focus on the United States was conducted and various perspectives were analyzed. Sources included books, websites, journal publications, news sources, government documents and publications, legal perspectives and information from biotechnology (biotech) companies.

Findings revealed that genetically modified food remains a controversial topic for public health, and includes environmental, health, and ethical issues. There is still much debate about the regulation and safety of these foods in general, and escalating concern with the possibility of the genetically engineered salmon being approved for entry into the food chain without data on the long term impacts on human health and the animal population.

Improved processes regarding the regulatory and safety review of genetically modified foods are necessary to safeguard the public and environment. The FDA is mandated to protect public safety, and FDA policies must put the safety of the public before the wishes of biotech companies, until the assurance of long term safety can be

improved. Therefore, improved regulation, including labeling of foods with genetically modified content, can protect consumers while allowing them to make informed personal choices.

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Preface

While working as a Registered Dietitian in Public Health, I became aware of a controversial trend regarding America's food supply. Biotechnology was having an increasing presence in the foods Americans consumed every day, and consumers were unaware of the change taking place over the years. Genetically modified organisms (or GMO's), had gradually become part of agricultural crops, but there was a new item awaiting approval at the time this paper was being written: the genetically modified salmon, the first genetically engineered animal that would become part of our food supply.

Viewed as a positive contribution by some, but as negative by others, I was intrigued as to how the story of this genetically modified (GM) salmon would unfold. Was the United States of America ready for this next step in science and history? Was it safe from a public health perspective? I wondered whose decision it would be to approve this new food for our consumption and how would conclusions be formed? Would I eat it, and will consumers have adequate information available to enable them to make informed choices? As a public health leader, I want to be prepared with accurate information for myself, and when asked questions about genetically modified foods by others.

This paper will summarize the current issues regarding the new salmon, and formulate hypothetical policy recommendations that would satisfy the regulatory agencies, and provide fair and supportive requirements for producers. Ultimately, the goal of the GM salmon policies will be to assure safety for consumption and provide increased peace of mind for consumers in the United States.

I will be watching, along with the rest of the country, to see if the salmon may become a genetically modified main course offered for our dinner tables soon. If it is approved, we will have to decide if it is a good choice for ourselves, our families, and our nation.

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Abbreviations

APHIS- Animal and Plant Health Inspection Service

Biotech- biotechnology company/companies

BSE- Bovine Spongiform Encephalopathy

CFR- Code of Federal Regulations

CFSAN- Center for Food Safety and Applied Nutrition

DCP- Department of Consumer Protection

DDT- dichlorodiphenyltrichloroethane

EIS- Environmental Impact Statement

EPA- Environmental Protection Agency

ESA- Endangered Species Act

FDA- Food and Drug Administration

FDCA- Federal Food, Drug and Cosmetic Act

FDAAA- Food and Drug Administration Amendments Act

FONSI- Findings of No Significant Impact

GE- genetically engineered

GM- genetically modified

GMO- genetically modified organism

GRAS- Generally Recognized As Safe

HB- House Bill

HR- House Resolution

NAD- New Animal Drug

NADA- New Animal Drug Application

NEPA- National Environmental Protection Act

OSTP- White House Office of Science and Technology Policy

PCBs- Polychlorinated biphenyls

rBGH- recombinant bovine growth hormone

rDNA- recombinant Deoxyribonucleic acid

sec - section

sHB- Substitute House Bill

USC - United States Code

USCA - United States Code Annotated

USDA- United States Department of Agriculture

VMAC- Veterinary Medicine Advisory Committee

Introduction

Genetic modification of crops and animals has a long and controversial history, but has increasingly touched on public health issues over the past several decades. Genetic engineering challenges moral, political, personal, ethical (Olesen, Myhr, & Rosendal, 2010), and even religious beliefs and values (Federici, n.d.), while pushing the limits of science and biotechnology. Some feel that GM of food is a solution to many of the world's food and related public health issues (BBC News, 1999; Coghlan, 2010; Lomborg & Post, 2013) while certain countries have said a loud 'no' due to related concerns (Federici, n.d.). In the United States, however, the debate is still going strong, but has become more heated as regulatory agencies develop policies regarding controversial genetically modified (GM) animals with the potential to enter the food chain (Homer, 2011). Because the long term human health impacts of GM foods are not fully known, this is a serious decision that has the potential to affect everyone living in the United States. Genetic modification of the salmon has put the spotlight on the battle of government regulation versus free enterprise (Homer, 2011). This paper will explore the relevant issues, examine several perspectives, and suggest policy recommendations designed to improve protection of the public's health in this country.

Theoretical Perspective

People in the United States may be unaware of the process that underlies assuring the safety of our food supply and environment. Some may believe that the regulatory bodies have the most accurate information about safety and potential problems with new food products, and will protect us from all harm. Others may trust that genetically

modified foods may be better for us than their non-modified counterparts, and assume that there is not any health or environmental risks involved with the GM foods, specifically the salmon. I propose that the current regulatory system has not adequately addressed all the aspects of the pending GM salmon approval, as evidenced by the number of unresolved issues, for example, inadequate environmental assessment by the FDA, unresolved labeling controversies, lack of long term health data, and regulatory classification issues. Improvements to the regulation and labeling of the GM salmon should address the concerns of consumers and stakeholders (Mason, Leavitt, & Chaffee, 2007), define specific guidelines for safety, correct any shortcomings of current regulatory processes, and implement policies that will educate and protect consumers.

Methods

A literature search revealed a great deal of information about the history, issues, controversies, stakeholders and policies surrounding GM foods, particularly the GM salmon in the United States. The search was completed in three phases to educate myself on the history of GM foods in general, including the scientific background of GM foods, biotech companies, consumer concerns, regulatory agencies, labeling issues and political controversies surrounding the topic. Key search terms used were 'genetically modified foods basics', 'genetically modified foods and (basics or overview)', 'GMO foods labeling', 'GMO foods Monsanto', 'start of GMO foods', 'battle brewing over labeling of genetically modified food', 'should GMO foods be labeled US' (parameters: since 2012), 'GMO foods FDA', and 'GMO salmon'. Due to the quickly changing developments surrounding the topic, particularly the GM salmon, grey literature was

included in the search to obtain information regarding current developments, issues, and global news events about GM foods.

Results

The first search utilized the following search engines: *Articles +*, *Lexis Nexis Academic*, *Google Scholar*, *Google*, and the *UNC Health and Sciences Library Catalog*, and revealed thirty seven sources (see Appendix A), and some notable information:

- Many consumers are not likely aware they are already consuming GM foods. By 2011, 88% of corn and 94% of soybeans were genetically modified, while 70-75% of processed foods contained genetically modified ingredients (United States Department of Agriculture [USDA], 2011).
- There is documented concern that a prominent member of the Food and Drug Administration (FDA), Michael Taylor, the Deputy Commissioner of Foods, was previously employed by Monsanto, and may be influential in FDA decisions, and putting the demands of the biotech giant before the safety of the public (Flock, 2012; Robin, 2010).
- As documented by Dahl (2012), six European countries have banned the cultivation and import of GM foods, and fifty nations have labeling requirements for GE food products (Dahl, 2012)

Several books were reviewed that dealt with controversial issues such as labeling requirements (Marchant, Cardineau, & Redick, 2010) and the history of GM foods and biotech companies, mainly Monsanto, which was formerly a chemical company (Robin, 2010). The issues discussed in these sources included:

- Biotech companies developed and have been responsible for dioxin (a component in the herbicide more commonly referred to as Agent Orange) that is associated with identified diseases and birth defects (United States Department of Veterans Affairs, 2013), as well as the now banned insecticides DDT/PCB's (Environmental Protection Agency [EPA], 2012; Environmental Protection Agency [EPA], 2013).
- NutraSweet® (aspartame), Roundup®, and Posilac® bovine growth hormones (rBGH), which are not banned, but have had controversial pasts due to various concerns regarding human and animal health issues, have also been produced by biotech companies (Robin, 2010).
- Monsanto owns 90% of the patents for GM crops, including the patents for the herbicide Roundup® and Roundup Ready® seeds, which can be planted and will germinate almost immediately after the Roundup® herbicide application; these GM seeds cannot be saved by farmers who may typically save part of a harvest for seeds (Robin, 2010). Monsanto's GM crops have been blamed for the collapse of pollinating bees (The Star [Nairobi], 2013).
- Robin (2010) highlights the concerns of this biotech giant's past products, some of which were originally approved as safe, but later were deemed harmful after the company made huge economic gains. This negative history has raised concerns that GM crops, as well as the GM salmon may not be safe enough for human consumption.

It was a challenging search and difficult to find information that had limited bias, due to the tendency of many sources to be polarized on certain issues. Specifically

regarding the GM salmon, if approved, it will be the first genetically modified animal approved for human consumption in the United States (Pollack, 2010).

One extremely valuable resource was a well-referenced 54 page journal article from the peer reviewed Columbia Journal of Law and Social Problems (Homer, 2011), titled “Frankenfish...It’s What’s for Dinner: The FDA, Genetically Engineered Salmon, and the Flawed Regulation of Biotechnology”, which cited many sources, some of which led to additional resources for this paper. Another informative resource was an academic paper titled “The Debate on Labeling Genetically Modified Foods” by a team of students from the University of Iowa; however, sections were poorly cited, making it difficult to determine the original sources of information (Damery, D’Adamo, Graham, Hoffman, & Riedl, 2011).

A second round of searches (See Appendix B) focused on government websites to locate documents, bills, and information regarding regulatory agencies and processes, history, national laws, state laws and upcoming issues of debate. Search terms included ‘CDC genetically modified foods’, ‘FDA GM salmon’, and various related searches for timelines and supporting documents. The FDA website <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/default.htm> (Food and Drug Administration [FDA], 2012a) provided the most timely information on the status of the GM salmon and public information on GM foods. In addition, it was necessary to research information about current regulation of food products and the approval process. The most significant document was *GFI #187 Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs* (Food and Drug Administration [FDA], 2009b).

As the search deepened, the topic evolved from GM food labeling issues to public safety after it was discovered that new GM food labeling laws were becoming effective in Connecticut on October 1, 2013, with bills in other states in the works. It should be noted that food labeling does not guarantee public safety, but provides one measure that empowers the public to make informed choices for themselves and their families. Based on these findings, the search focus then became the safety assurance of genetically modified salmon. Additional sources were pulled from the original articles identified by the initial literature search findings listed in Appendix A. The review of these additional sources revealed that there are many public health issues under debate regarding GM foods, including environmental, health, and regulatory considerations. Appendix C lists these additional sources that were cited by those from initial searches.

Background

Genetic manipulation of organisms is not a new technology. At first, it was nurtured to develop crops with improved yield or resistance to negative environmental effects (Halford & Shewry, 2000). Plants were first studied and then efforts evolved to animals in the 1980's (gmeducation.org, n.d.), and the topic of genetically modified organisms became more controversial as it challenged cultural values, the regulatory framework and political issues such as international trade (Vàzquez-Salat, Salter, Smets, & Houdebine, 2012). Appendix D provides a comprehensive list of significant dates in the history of genetically modified foods. Today, food biotech companies remain at the center of the controversy, plagued by accusations of putting the safety of the consumer

behind monetary gain, monopolizing the seed industry, and unfair practices toward farmers (Flock, 2012; Oloya, 2010; Robin, 2010).

In the United States, GM crops and vegetables have been gradually introduced to consumers, but the GM salmon is raising more concern due to uncertainties with its safety (Homer, 2011), that relates to issues about the regulatory processes for genetically modified food approval and monitoring in the United States, and encourages scrutiny of the current policies.

What exactly is genetically modified salmon? The experts have noted that genetically engineered salmon is created by adding genes from the Chinook salmon and the Ocean Pout to the Atlantic salmon. This modification allows the salmon to produce growth hormone all year round, instead of the natural partial year, and speeds up growth to market size of 3-4 kilograms in 18 months instead of 24-30 months as shown in Figure 1 (AquaBounty Technologies, 2013b; Office of Science & Technology Policy, 2001).

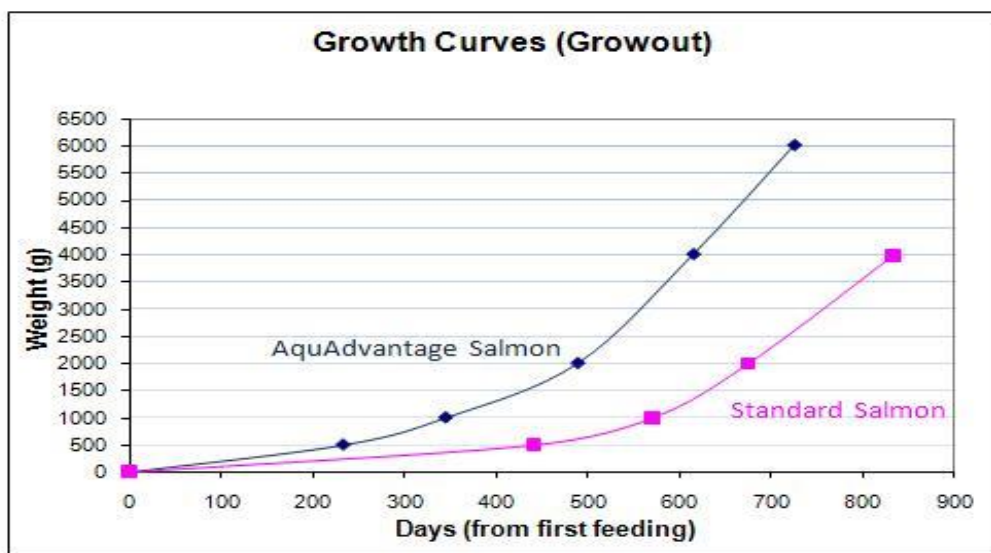


Figure1. Growth Comparison of AquAdvantage Salmon to Standard Salmon (AquaBounty Technologies, 2013b)

Potential benefits of GM salmon:

Genetically modified salmon have positive potential, and could even help meet an increased demand for salmon and protect wild fish stocks (some salmon populations are endangered now) (Veterinary Medicine Advisory Committee, 2010). They require less feed and can be sold more quickly (AquaBounty Technologies, 2013a).

In addition, GM salmon farming can lessen the carbon footprint of overfishing and production (AquaBounty Technologies, 2013c), and has the potential for increased investments in the product, helping the US economy (AquaBounty Technologies, 2013c). Aquaculture in the United States currently generates approximately one billion dollars annually (Goldburg, Elliot, & Naylor, 2001). The GM fish provide increased economic efficiency and profits for commodity fish producers (Clausen & Longo, 2012) and may help meet food demand globally (BBC News, 1999; Homer, 2011). According to Menozzi et al. (2012), if the GM salmon is accepted by consumers it may be less expensive, thus resulting in increased intake. Finally, an increase in Omega 3 fatty acids may improve health, especially those of lower socioeconomic status, in turn improving public health (McLaren, 2007; Smith, Asche, Guttormsen, & Wiener, 2010).

Regulation, Current Policies and Evolution of the Current Regulatory Process

Before analyzing the current regulatory agencies and their policies, it is important to understand how the policies were developed, and lead to the resulting challenges we face today with the GM salmon. During the 1980's, regulatory agencies had overlapping responsibilities, which led to confusion when biotechnology emerged. The Domestic

Council Policy Working Group was formed, along with the White House Office of Science and Technology Policy (OSTP) (PewTrusts.org, 2001). The Coordinated Framework for Regulation of Biotechnology was developed (Office of Science & Technology Policy, 1986; PewTrusts.org, 2001); Homer (2011) highlights the fact that the framework has changed little since 1980's, and decisions reached by this entity are not legally binding. The Coordinated Framework had agencies base decisions and regulations on outdated laws created prior to advances in biotechnology. In fact, the Coordinated Framework concluded that "(GM) products are not inherently riskier than their natural analogs, and, therefore, that (GM) products can be adequately regulated by the pre-existing statutory and regulatory structure", which are the same regulations as for the conventionally produced counterparts (Office of Science & Technology Policy, 1986).

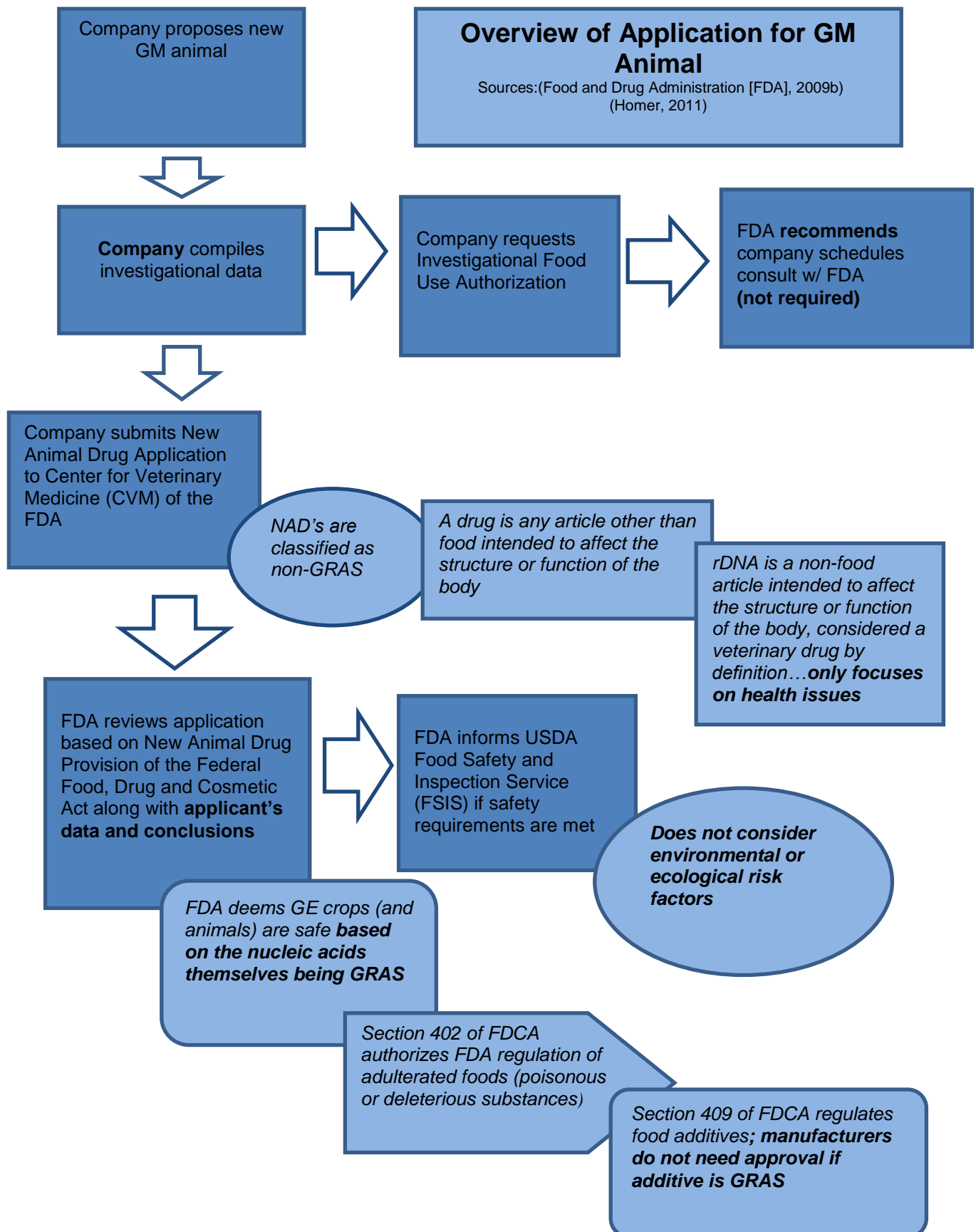
No single agency became solely responsible for both the evaluation of safety and regulation of the production of GE foods based on interpretation of previous laws (PewTrusts.org, 2001). The FDA is supposed to oversee food safety of all GE food products for human consumption (National Research Council, 2002) based on the Federal Food, Drug and Cosmetic Act (FDCA) of 1938 (United States House of Representatives, 1938). Further, Section 402 of the FDCA authorizes regulation of adulterated foods (poisonous or deleterious substances), and Section 409 of the FDCA regulates food additives, but manufacturers do not need FDA approval if an additive is Generally Recognized As Safe (GRAS) (United States House of Representatives, 1938). In 1992, the FDA issued the "Statement of Policy: Foods Derived from New Plant Varieties" (Food and Drug Administration [FDA], 1997). The FDA presumed GE crops

were safe based on the fact that nucleic acids added to these crops were GRAS, and left it up to manufacturer to be responsible for product safety, making most GE foods exempt from safety reviews. In 1996 and again in 2006, the FDA published guidance for producers to voluntarily consult with them before marketing GM foods. The FDA consultation was to evaluate the developers' conclusions and only considers human risk, not environmental or ecological (Food and Drug Administration [FDA], 1997).

As GE animals were being developed, in 2009, the FDA issued "Guidance for Industry 187: Regulation of Genetically Engineered Animals Containing Heritable Constructs" (Food and Drug Administration [FDA], 2009b) and claimed regulatory authority over GE animals under FDCA's "new animal drug" authority (as the FDA also regulates pharmaceuticals for humans and animals per the FDCA) (United States House of Representatives, 1938).

To initiate the process, the developer files a New Animal Drug Application (NADA), for a drug to be used in any animal other than a human, including drugs in animal feed (United States House of Representatives, 1938) see Figure 2. The definition of a drug is any article other than food intended to affect the structure or function of the body (both animals and human) (United States House of Representatives, 1938).

Figure 2. Model of GM Animal Approval Process



An Engineered Recombinant DNA (rDNA) construct is a non-food article, intended to affect the structure or function of a GE animal, and considered a veterinary drug by definition, and focuses only on health issues, not environmental (Mandel, 2004). FDCA's definition of a "new animal drug" specifies the drugs are not 'GRAS', conflicting with the food aspect of GM foods being GRAS (rDNA added to crops is GRAS while rDNA added to animals is not GRAS because of the NAD status (United States House of Representatives, 1938). GE animal food products are under veterinary drugs, and reviewed by the Center for Veterinary Medicine (CVM) rather than Center for Food Safety and Applied Nutrition (CFSAN) (Food and Drug Administration [FDA], 2009) the consequence of GM foods being classified as a new veterinary drug (Mandel, 2004).

Due to the Trade Secrets Act, the FDA could not reveal information acquired through the NADA process (Americans usually do not know much about a product until its release) (Office of Science & Technology Policy, 2001; Pollack, 2010), putting limits on transparency. In 1995, AquaBounty, the company that intends to supply GE salmon eggs to fish farms (Food & Water Europe, 2010), submitted information on ten generations of their GE AquaAdvantage salmon, and the CVM (Center for Veterinary Medicine) held the Veterinary Medicine Advisory Committee (VMAC) meeting to release preliminary public information, and obtain outside expert advice. (Naik, 2010).

The FDA's position was that the 2007 Food and Drug Administration Amendments Act (FDAAA), the Endangered Species Act (ESA), and the National Environmental Protection Act (NEPA) gave them authority to regulate environmental aspects of the GM salmon (Office of Science & Technology Policy, 2001), and this was reinforced by information submitted by Aquabounty assuring containment of the GM salmon (Homer,

2011). This position was undertaken to fill the gaps of the other agencies since the Environmental Protection Agency (EPA) interprets its regulation over the environmental risks, but no regulatory authority over GE animals (Mandel, 2004), and the USDA Animal and Plant Health Inspection Service (APHIS) only monitors the health of GM livestock, completes inspections before and after slaughter, and monitors GM veterinary medicine products (Vázquez-Salat, Salter, Smets, & Houdebine, 2012). In the case of the GM salmon, the FDA has issued a Findings of No Significant Impact (FONSI) status but no complete Environmental Impact Statement (EIS) (Food and Drug Administration [FDA], 2010). To some, this appears as 'foot dragging' approval of GM salmon (Noah, 2013). As a result, there is no federal agency effectively handling the environmental impact aspect to the safety of these GM consumer foods (Homer, 2011).

An additional concern about GE regulation is that in 2013, HR 933 section 735 was passed, which protects biotech companies by allowing them to continue selling GM seeds while legal action may be in process against them, and continue sales even if the crops are deemed harmful to humans (United States Congress, 2013). This resolution was controversial because it was 'slipped in' with a larger bill, according to some (Gibson, 2013), and puts the interest of biotech companies ahead of the assurance of safety by the regulatory authorities. The bottom line is not only are the regulations based on limited data, but because of the different regulatory jurisdictions, there remain gaps in assessing and evaluating the full impact of GM salmon on humans and the environment.

The FDA has divided genetically modified animals into six categories:

- 1) Produce pharmaceuticals to be used for other animals and humans

- 2) Decrease the environmental impact of large-scale agricultural practices by decreasing the amount of chemicals such as phosphate in manure, thereby reducing water pollution
- 3) Serve as a source of cells, tissue, and organs closely matched to humans so that they may be able to be transplanted into humans without rejection
- 4) Produce high value materials such as those used for surgical sutures and personal protection devices such as body armor for military and law enforcement use
- 5) Produce highly specific antimicrobials that cause disease-causing bacteria such as *E. coli* 0157:H7 or *Salmonella*
- 6) Provide more healthful or more efficiently produced food (Food and Drug Administration [FDA], 2012b).

If approved, the GM salmon would be the first GE fish approved for human consumption in the United States (Bratspies, 2005; Erickson, 2009; Homer, 2011; Pollack, 2010; Voosen, 2010).

Current Controversies

Health Concerns: Short and Long Term- Too Early for Approval?

According to the US Genome Program, the human health impacts from GM food products are not fully known, as stated earlier (US Department of Energy Genome Program, 2012). There are concerns about the risk of exacerbated allergies in humans who consume GM products (Goodman & Tetteh, 2011; US Department of Energy Genome Program, 2012; Winter, C. K., Gallegos, L. K., 2006), and also that negative animal feeding studies showing toxicity and resulting organ problems may not have been reported or not reported accurately (Robin, 2010).

Due to problems with other GM food sources, previous GM crops have been removed from production (Starlink® corn) or not allowed to enter production (GM potato), (Winter, C. K., Gallegos, L. K., 2006), it is possible that GM animals may be similar. Allowing a GM animal into the food chain is perceived as risky at this time,

considering there are still unknown effects (Farquhar & Meyer, 2007; US Department of Energy Genome Program, 2012).

An article by Seralini et al. (2011) suggests that results of some tests on the health effects of GM crops on animals have not been adequately interpreted and disclosed. The article concluded that additional, longer, and more thorough testing is ethically necessary, along with post-market monitoring for human populations already exposed (Séralini et al., 2011). According to Menozzi et al, experts “speculated that consumer health is more likely to be harmed than improved by GM salmon” (Menozzi, Mora, & Merigo, 2012).

As documented by Spiroux De Vendomois et al., additional studies have demonstrated that the GM salmon is not as nutritious as its traditional counterpart (gefish.org, n.d.), and it may lead to complications with substance toxicities, and further antibiotic resistance, especially if the salmon ingest GM feed products (Spiroux De Vendômois, Roullier, Cellier, & Séralini, 2009).

Have environmental concerns been adequately evaluated?

There are also potential negative risks with the GM salmon to be considered. Escape risk from facilities, leading to potential mating with wild populations, could damage or even cause extinction of wild salmon populations and other wildlife (Howard, DeWoody, & Muir, 2004). Sterilization (triploidy) has been shown to be effective in only 95% of AquaBounty’s GM salmon eggs (Food and Drug Administration [FDA], 2010) Although difficult to estimate, researchers have concluded that other invasive species (for example, Asian carp) have caused environmental damages up to an estimated \$120 billion per year, including interference with the fishing industry, clogging dam systems,

attacking other species of aquatic life, and the resulting expenses from controlling such invasions (Eilperin, 2010). Devlin et al. expose the concerns regarding the potential of problems with escaped GM salmon could have other devastating environmental effects (Devlin, D'Andrade, Uh, & Biagi, 2004).

The same study by Devlin et al. revealed some GE salmon are more aggressive and sometimes resort to cannibalism during periods of low food supply (Devlin et al., 2004). These situations could cause unpredictable impacts on an ecosystem (Farquhar & Meyer, 2007; National Research Council, 2002). Farmed GM salmon may require large amounts of antibiotics (Naik, 2010), which could lead to antibiotic resistance (US Department of Energy Genome Program, 2012). Others have indicated that GM salmon farming will reduce preservation and restoration of wild fisheries (Clausen & Longo, 2012). There are environmental safety concerns based on the history of previous tragic biotech company chemical incidents such as Agent Orange, DDT and PCB's (Environmental Protection Agency [EPA], 2012; Environmental Protection Agency [EPA], 2013; Robin, 2010; United States Department of Veterans Affairs, 2013) which have led to questions about adequacy of safety assessments and practices by biotech companies. Since the GM Salmon farms are to be located in other countries such as Panama (The Development Fund, 2013), it is likely that these farms cannot be monitored closely by the FDA and USDA.

Inappropriate Classification for Regulatory Review

The current regulatory process for GM foods was devised while only agricultural products were being developed and GM animals were under consideration for uses that did not include human food consumption, as discussed under the Evolution of the

Current Regulatory Process section (also refer to Appendix D). From my determination, the FDA has not adequately consulted with other federal agencies concerning the GM salmon, since they have completed a FONSI, but not an EIS for AquAdvantage Salmon (Food and Drug Administration [FDA], 2010). Therefore, the FDA has not completed a full environmental assessment, and is not the appropriate agency to do this based on the FDAAA. Likewise, critics feel that the VMAC and CVM are not the appropriate agency to evaluate this salmon in terms of food safety (Homer, 2011). Since the approval of the GM salmon could establish the regulatory review precedence and open the door for other GE food animals for human consumption (Homer, 2011), adequate completion of each of these assessments and complete evaluation of these data are vital before the GM salmon possibly becomes a large part of our food supply.

Unresolved Consumer Choice Issues: Labeling of the GM Salmon

Some stores have announced they will reject GM seafood (Friends of the Earth, n.d.), and it has been postulated that other countries will likely reject imports of the GM salmon (Dahl, 2012). These decisions appear to be based on the knowledge that many still prefer knowing salmon is wild caught as opposed to farmed salmon (Clausen & Longo, 2012).

There continues to be controversy over whether or not GM foods should be labeled in the United States (Marchant, Cardineau, & Redick, 2010). Groups who support labeling include concerned US consumers (Marchant et al., 2010), those who wish to avoid GM salmon for religious reasons, special interest groups, producers of non-GMO foods, stores that refuse to carry some GM products (Friends of the Earth, n.d.), supporters of California Proposition 37 and the California Right to Know Genetically

Engineered Food Act (Dahl, 2012), as well as individual states such as Connecticut (State of Connecticut, 2013). The consumer's right to know is the basis for this position.

There are also groups against labeling of GM foods, including GMO food manufacturers (Federici, n.d.), biotech companies (Dahl, 2012; Robin, 2010), agribusiness (Dahl, 2012), and some grocery stores (Dahl, 2012). Their position is based on the concern that labeling GM foods will cause a decrease in sales and is due to unwarranted concern about the safety of the food products (Marchant et al., 2010).

Discussion

Potential approval of the GM salmon still remains a controversial subject in regards to public health issues such as assurance of human safety, environmental concerns, consumer acceptance and regulation. The GM salmon offers potential benefits, but it is still undecided if they are outweighed by the potential costs and risks, both known and unknown.

After a difficult battle, Connecticut was the first US state that passed laws that will require most GM foods to be labeled, as documented in substitute House Bill 6527 (sHB 6527) (State of Connecticut, 2013). The bill includes the labeling of applicable seeds and seed stock, as well as infant formula and baby food. It does not apply to "(1) alcohol, (2) food not packaged for retail sale that is intended for immediate consumption, and (3) certain farm products". In addition, the bill excludes any GM food to be marketed as "natural", non-GM animals that were fed GM products, some foods processed with GM processing aids or enzymes, and foods that contain less than 0.9% total weight GM materials before July 1, 2019. The law subjects knowing violators of this

mandate to label the identified GM foods to a daily fine of up to \$1,000 per day, and violators can face criminal charges. The Connecticut State Department of Consumer Protection (DCP) will be permitted to seize food or place embargos on foods (State of Connecticut, 2013). The amendment adds a defense for retailers who have relied on the disclosure of wholesalers. Several other states are working on the development of labeling laws for GM food products, but there are pros and cons of the labeling concept.

PROS of Labeling GM Foods:

Appropriately labeling GM foods will result in better informed consumers, allowing them to make better choices, according to the opinion of Marchant et al., (2010). It may ease lack of confidence in the regulatory system since the emergence of the bovine spongiform encephalopathy (BSE) (BBC News, 1999), because it increases transparency (Zhang, 2013) GM foods may contain potential allergens (US Department of Energy Genome Program, 2012), therefore labeling could help decrease exposure and, afford ease of shopping to avoid risky products for some individuals (Zhang, 2013). Accurate labeling could also improve international trade relations so other countries can more easily identify GM versus non-GM products to comply with individual countries' differing labeling regulations (Teisl & Caswell, 2003).

CONS of Labeling GM Foods:

Some feel labeling will cause unwarranted concern over products that are actually safe (Marchant et al., 2010), resulting in avoidance of GM foods (Zhang, 2013). Additional labeling requirements would increase expenses for food producers (Dahl, 2012; Marchant et al., 2010; Zhang, 2013), resulting in increased food prices (Marchant

et al., 2010). In addition, failure to comply with FDA labeling regulations can result in legal action and delayed production (Food and Drug Administration [FDA], 2009a).

The book Thwarting Consumer Choice, The Case Against Mandatory Labeling of Genetically Modified Foods by Marchant, Cardineau and Redick (2010), suggests the best option would be voluntary labeling of GM foods. This option still does not address the fact that some consumers are not as informed about the GM salmon, especially, and may be at risk for issues that may not yet have been identified.

On the other hand, a managed program (discussed later under Recommendations) could provide increased consumer education along with labeling standards, while still supporting the progress of GM foods (Federici, n.d.; Teisl & Caswell, 2003). This approach could also calm the battle between biotech companies, regulatory agencies, and the public in the United States.

Recommendations

Consumer protection can be assured by strengthening public health policies. Regulatory agencies must put the health and well-being of consumers before the wishes of food biotech companies. This may cause further delay in the approval of the GM salmon, but it is imperative that assurance be provided before the approval process is completed. I recommend improved regulatory coordination and policies, further safety and environmental testing, and consistent labeling requirements for GM products prior to the approval of the GM salmon.

Assurance of Human Safety

The FDA should be responsible for evaluating the food safety aspects of the GM salmon, and not leave this aspect to interpretation based on the manufacturers' conclusions alone. In addition, it should be evaluated as a non-GRAS human food product, not only as an animal veterinary drug. Partnering with the EPA to be responsible for environmental evaluations, combining expertise, and improving coordination between agencies will be essential to direct the required assessments. Further, the FDA should mandate research and evaluation from outside evaluating agencies and the manufacturers (such as by clinical research organizations), whereby these data are submitted directly to the FDA, bypassing manufacturers who could omit or change unfavorable data. This will also divert development and evaluation costs of GM foods to the biotech companies who will ultimately profit instead of government/tax payer funded evaluation. Evidence based research should be used to inform policymakers (Brownson, 2009), while controlled animal studies, all the way through to voluntary approved human studies should be required. The approval of the GM salmon for human consumption should be delayed until studies with a longer duration have been conducted and the results independently analyzed and reported. Lengthier, multi-generational animal testing, combined with improved statistical analysis methods will help more appropriately analyze results of GM feeding trials (Séralini et al., 2011), in animals, then humans, and should be required by the FDA before the release of the GM salmon for widespread human consumption. If the GM salmon is approved, long term human health monitoring should take place among consumers using risk-based

monitoring to more effectively identify abnormal trends or issues (Food and Drug Administration [FDA], 2013).

Protecting the Environment

The FDA should combine efforts with the EPA to complete the more thorough full environmental assessment (EIS or Environmental Impact Statement) before providing their recommendation for the approval of the GM salmon. It would be beneficial for the USDA to continue to support research regarding the inability of the female GM salmon to reproduce (reaching a reproducibility level of 0% as compared to the current 5%), to build upon an earlier USDA research grant to AquaBounty for this purpose (United States Department of Agriculture [USDA], 2011). Requirement of special permit licensing of GM salmon producers and distributors would help ensure compliance with standards, and help defer costs of the program to help ensure environmental safety. In addition, develop and institute specially licensed individuals to provide mandatory training for GM salmon farmers (similar to food service certification trainings). Pilot programs should only be allowed inside the borders of the United States at this time so fisheries can be monitored and regulated, with the possibility of expansion outside of the United States later. Finally, only inland fisheries should be permitted to prevent escape to bodies of water.

Alleviating consumer concerns

Increased transparency (Homer, 2011) will be necessary to help the consumer gain trust in the US regulatory system for genetically modified foods for human consumption. The conversation should be revisited for public input before approval of GM salmon (public input should also include comments/concerns from experts, input to legal and

academic areas on the FDA website and through focus groups at universities and at events such as law meetings). Consumer knowledge and education should be expanded to increase awareness of GM foods, and made available through local health education programs, social media, schools and food assistance programs.

Labeling standards for GM foods will allow consumers to make the best choices for themselves and their families. Ideally these standards should be national, instead of state by state, to avoid potential commerce issues if products are shipped to states with different labeling requirements. Strict labeling standards to identify GM foods should be required until additional long term studies to assess the impact of GM salmon and other foods on the environment and humans. Evaluation of GM food labeling standards should be undertaken after long term data are available.

A suggested alternative per the book Thwarting Consumer Choice (Marchant et al., 2010) is voluntary labeling, but this approach would still expose unaware consumers to possible harm. Basic, user friendly labeling, along with a consumer education program will educate unaware or fearful consumers while providing choices for individuals who wish to avoid GM salmon for health or other personal reasons. Combining efforts with the MyPlate.gov campaign, an already recognized website, could be a beneficial partnership. A pilot program focusing on consumer education about GM foods and labeling of such foods could be conducted and evaluated for effectiveness before full implementation nationwide.

Conclusion

Gradually, those living in the US have been exposed to more genetically modified crops over the years, and they have been reasonably accepted (Homer, 2011). With the potential for a GM animal, in particular the salmon, entering the food chain, GM foods and the accompanying issues and policies have taken on a new spotlight.

It is imperative that these issues are examined from a public health standpoint, and gaps in the regulatory approval and oversight process need remediation before problems, including potential health, environmental and ethical problems may result. Once the GM salmon is approved for human consumption, it will not be as easy to turn back the clock. At this time, the risk may be at a higher cost than the benefits (Food & Water Europe, 2010), and it is my view this is true for the United States. It is essential for public health leaders to be actively involved in the regulatory review process and associated policymaking, to safeguard the best interest of the public, before the genetically modified salmon becomes a mainstay in our food supply.

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Appendix A: Initial Literature Review: Source by Category

Initial Literature Review: Source by Category	PEER REVIEWED?	Biotech Companies	Regulatory Agencies	Labeling	GMO Basics	GM Salmon/Animals	Environmental/Farming	Media	Global Issues	Health Risks	Pros/Cons	Legal Issues	Safety Issues	Pharmaceuticals	Ethics	Policy
Africa News <i>Kenya; The genetically modified organism question: What is the truth?</i>	x						x		x							
Clausen, Rebecca <i>The tragedy of the commodity and the farce of AquaAdvantage Salmon</i>		x				x										
Cochrane, Paul <i>U.S. Food and Drug Administration: Over 1 million comments received by the FDA regarding GMO food labeling</i>			x	x									x			x
Coghlan, Andy <i>Vatican to support engineered crops</i>						x					x					
Dahl, Richard <i>To label or not to label: California prepares to vote on Genetically Engineered foods</i>	x			x								x				x
Damery, Phil et al <i>The debate on labeling Genetically Modified food</i>				x								x				x
Du, Dorothy <i>Rethinking risks: Should socioeconomic and ethical considerations be incorporated into the regulation of Genetically Modified crops?</i>	x														x	
Federici, V. <i>Genetically Modified food and informed consumer choice: Comparing US and EU laws</i>	x								x			x				
Flock, Elizabeth <i>Monsanto petition tells Obama: 'Cease ties to Monsanto'</i>		x	x													x
Frewer, Lynn J. et al <i>The media and genetically Modified Foods: Evidence in support of social amplification of risk</i>	x							x					x			
Goodman, Richard E. <i>Suggested improvements for the allergenicity: Assessment of Genetically Modified plants used in foods</i>										x						
Homer, Michael Bennett Frankenfish...It's what's for dinner: <i>The FDA, Genetically Engineered salmon, and the flawed regulation of biotechnology</i>	x	x	x			x	x			x	x	x	x			x
Kuiper, Harry A. et al <i>Assessment of the food safety issues related to Genetically Modified foods</i>	x												x			
Lomborg, Bjorn <i>Blind children; the unintended consequence of the anti-GMO movement: Golden rice can save millions from vitamin A deficiency, but its use has been</i>			x								x					

Initial Literature Review: Source by Category	PEER REVIEWED?	Biotech Companies	Regulatory Agencies	Labeling	GMO Basics	GM Salmon/Animals	Environmental/Farming	Media	Global Issues	Health Risks	Pros/Cons	Legal Issues	Safety Issues	Pharmaceuticals	Ethics	Policy
<i>blocked until now</i>																
Madin, Elizabeth M.P. <i>Genetically engineered salmon pose environmental risks that must be considered</i>	x					x	x									
Marchant, Gary E., Cardineau, Guy A., Redick, Thomas <i>Thwarting consumer choice: The case against mandatory labeling for Genetically Modified foods</i>			x	x						x			x			x
McHughen, A. <i>Pandora's picnic basket: The potential and hazards of Genetically Modified foods</i>											x					
McHughen, Alan Who's afraid of GMO's?; Don't let the activists scare you: Genetically modified foods are safe to grow and eat										x						
Mora, Cristina et al <i>Factors affecting the adoption of Genetically Modified animals in the food and pharmaceutical chains</i>	x					x								x		
Noah, Lars <i>Whatever happened to the "Frankenfish"? The FDA's foot-dragging on transgenic salmon</i>			x			x										x
Oleson, Ingrid et al <i>Sustainable aquaculture: Are we getting there? Ethical perspectives on salmon farming</i>	x					x									x	
Oloya, Opiyo <i>GM bill may not protect farmers</i>							x		x							x
Oloya, Opiyo <i>How much Has Monsanto paid scientists for the GMO experiments?</i>		x													x	
Pelletier, David L. <i>FDA's regulation of Genetically Engineered foods: Scientific, legal and political dimensions</i>	x		x									x				x
Pollack, Andrew <i>Genetically Engineered salmon get closer to the table</i>		x	x			x							x			
Pollack, M.A., Shaffer, G.C. <i>When cooperation fails: The international law and politics of Genetically Modified foods</i>									x			x				x
Prakash, C.S. <i>GM in the media</i>								x					x			
Qin, Wei and Brown, J.L. <i>Consumer opinions about Genetically Engineered salmon and information effect on opinions</i>	x					x										
Robin, Marie-Monique <i>The world according to Monsanto</i>		x	x							x			x			

[illegible]

Appendix B: Secondary Literature Review: Source by Category

Secondary Literature Review: Source by Category	PEER REVIEWED?	Timeline	Regulation	Core Functions/ Essential Services	Ethics	GM salmon/foods	Safety	Environmental
American Radio Works <i>History of Genetic Engineering</i>		X						
Centers for Disease Control and Prevention <i>Public health ethics</i>	X				X			
Devlin, Robert H. et al <i>Population effects of growth hormone transgenic coho salmon depend on food availability and genotype by environment interactions</i>						X		X
Food and Drug Administration Animal and Veterinary-FDA's response to public comments	X		X					
Food and Drug Administration <i>Guidance for industry: Regulation of Genetically Engineered animals containing heritable recombinant DNA constructs</i>	X		X			X		
Food and Drug Administration <i>Guidance for industry: Voluntary labeling indicating whether foods have or have not been developed using bioengineering; Draft guidance</i>	X		X					
gmeducation.org <i>A brief history of genetic modification</i>		X						
State of Connecticut Substitute House Bill 6527, Public act No. 13-183: An act concerning Genetically-Engineered food	X		X				X	
United States Patent and Trademark Office <i>2105: Patentable subject matter- Living subject matter [R-9]</i>	X		X					
Centers for Disease Control and Prevention <i>Public health core functions and 10 essential services</i>	X			X				

Appendix C: References Identified by Review of Literature and Additional Supporting Sources

References Identified by Review of Literature and Additional Supporting Sources	PEER REVIEWED?	Regulation	GM Salmon/Fish	Public Health Essential Services	Environmental
AquaBounty Technologies Press room #13: <i>Aquaculture facts</i>			x		
AquaBounty Technologies Press room #14 <i>Benefits of land based aquaculture systems</i>			x		
Bratspies, Rebecca M. <i>Glowing in the dark: How America's first transgenic animal escaped regulation</i>		x			
BBC News <i>GM food: Head to head</i>					
(The) Center for Food Safety <i>Food safety fact sheet: Genetically Engineered fish</i>			x		
Centers for Disease Control and Prevention (CDC) <i>The public health system and the 10 essential public health services</i>	x				
(The) Development Fund <i>Genetically engineered salmon: Fast growing hype (fact sheet)</i>			x		
Devlin, H.D. et al <i>Population effects of growth hormone transgenic coho salmon depend on food availability and genotype by environment interactions</i>	x		x		x
Environmental Protection Agency <i>Basic information about polychlorinated biphenyls in drinking water</i>	x	x		x	x
Environmental Protection Agency <i>DDT- A brief history and status</i>	x	x		x	x
Erickson, Britt <i>FDA approves drug from transgenic goat milk</i>	x	x			
Eilperin, J. <i>Tough choices follow in the wake of many invasive species</i>				x	x
Farquhar, Doug and Meyer, Liz <i>State authority to regulate under the Coordinated Framework</i>		x			
Food and Drug Administration	x	x			

References Identified by Review of Literature and Additional Supporting Sources	PEER REVIEWED?	Regulation	GM Salmon/Fish	Public Health Essential Services	Environmental
<i>Food labeling guidance</i>					
Food and Drug Administration <i>Guidance on consultation procedures-Foods derived from new plant varieties (1996/1997)</i>	x				
Food and Drug Administration <i>FDA statement regarding Glofish</i>	x	x			
Food and Drug Administration <i>Guidance on consultation procedures: Foods derived from new plant varieties</i>	x	x			
Food and Drug Administration <i>VMAC briefing packet: AquAdvantage Salmon</i>	x	x	x		
Food & Water Europe <i>Issue brief: GE salmon will not feed the world</i>			x		
Friends of the Earth <i>Campaign for GE-Free seafood</i>			x		
Ge-fish.org, Center for Food Safety <i>Nutrition facts AquAdvantage Salmon</i>			x		
Goldburg, R. et al <i>Marine aquaculture in the United States: Environmental impacts and policy options</i>		x	x		x
Green Groups letter <i>Letter to FDA Commissioner Margaret Hamburg</i>		x	x		x
Halford, N. and Shewry, P. <i>Genetically modified crops: methodology, benefits, regulation and public concerns</i>	x				x
Howard, R.D. et al <i>Transgenic male mating advantage provides opportunity for Trojan gene effect in fish</i>	x		x		
Katch, Victor <i>Do we really need or want Genetically Modified foods?</i>			x		
Mandel, Gregory N. <i>Gaps, inexperience, inconsistencies, and overlaps: Crisis in the regulation of Genetically Modified plants and animals</i>		x	x	x	x
McLaren, Lindsey <i>Socioeconomic status and obesity</i>	x				
Menozzi, D. et al <i>Genetically modified salmon for dinner? Transgenic salmon marketing scenarios</i>			x		
Naik, Guatam <i>Gene-Altered Fish Close to Approval</i>		x	x		
National Research Council <i>Environmental effects of transgenic plants; the scope and adequacy of regulation</i>	x				
Office of Science & Technology Policy <i>Case study #1: Growth enhanced salmon</i>	x				

References Identified by Review of Literature and Additional Supporting Sources	PEER REVIEWED?	Regulation	GM Salmon/Fish	Public Health Essential Services	Environmental
Office of Science & Technology Policy <i>Coordinated framework for regulation of Biotechnology, 51 Fed. Reg. 23,302</i>	x				
OLR Bill Analysis <i>SHB 6527 (as amended by house "A" and senate "A"), an act concerning genetically engineered baby food</i>	x				
PewTrusts.org <i>The Pew initiative on food & biotechnology, Guide to U.S. regulation of Genetically Modified food and agricultural biotechnology: Product 5</i>		x			
Serelini et al <i>Genetically modified crops safety assessments: present limits and possible improvements</i>	x	x			
Spiroux, de Vendomois, Joel et al <i>A comparison of the effects of three GM corn varieties on mammalian health</i>	x			x	x
Teisl, Mario F. and Caswell, Julie A. <i>Information policy and Genetically Modified food: Weighing the benefits and costs</i>		x	x		
Tester, M. <i>GM food tarnished by urban myths</i>					
United States Department of Agriculture <i>USDA ERS adoption of genetically engineered crops in the U.S.</i>	x	x			
United States Department of Energy Genome Program <i>Genetically modified foods and organisms—HGP ethical, legal, and social issues</i>	x				
United States Department of Veterans Affairs <i>Agent Orange</i>	x	x		x	x
Veterinary Medicine Advisory Committee <i>An overview of Atlantic salmon, its natural history, aquaculture, and genetic engineering</i>	x		x		
Voosen, Paul <i>Panel advises more aggressive FDA analysis of engineered salmon</i>		x	x		

Appendix D: Significant Dates in the History of Genetic Modification of Food

1865- Gregor Mendel's research on breeding of peas is published, which became the basis for modern genetics (gmeducation.org, n.d.)

Prior to 1900- Seed saving from plants found in nature and crops, and natural hybrids among related plant varieties begin to be recognized by farmers and naturalists (American Radio Works, 2013)

1931- Barbara McClintock and Harriet Creighton examine maize microscopically and show evidence of physical recombination (linking of DNA from different chromosomes) (gmeducation.org, n.d.)

1973- Stanley Cohen and Herbert Boyer develop DNA cloning, allowing the transplant of genes between different biological species. The same year, the Ti plasmid in a bacteria is identified that can be used as a medium to genetically alter plants (gmeducation.org, n.d.)

1974- The first genetically modified organism is created (gmeducation.org, n.d.), and the evolution of Recombinant DNA technology allows genetic engineers to create highly controllable and predictable breeding outcomes (Homer, 2011)

1975- The United States holds a private conference with scientists to decide on self-regulation guidelines and the future path of genetic engineering (gmeducation.org, n.d.)

1976- The NIH develops guidelines for GM research (gmeducation.org, n.d.)

1980- US Supreme Court rules GM lifeforms can be patented in *Diamond vs. Chakrabarty* (American Radio Works, 2013; uspto.gov,)

1980- First genetically modified animal is created (mouse), and a domestic animal (pig) in 1985 (gmeducation.org, n.d.)

1992- USDA approves Calgene's Flavr Savr tomato for commercial production (American Radio Works, 2013)

1992- FDA declares genetically modified foods do not need any additional regulations and are not inherently dangerous (American Radio Works, 2013)

1994- Plant in vitro fertilization done on corn (gmeducation.org, n.d.)

1995- EPA approves use of the first pesticide producing crop (potato) and insect resistant corn in the US, and tobacco developed to produce hemoglobin (protein in human blood) (gmeducation.org, n.d.)

1996- Monsanto's Roundup Ready soybeans introduced in US, which will grow in glyphosate treated soil (gmeducation.org, n.d.)

1998- First patent issued for genetically modified seeds with 'Terminator Technology', preventing saved seeds from reproducing (gmeducation.org, n.d.)

2002- Biotech industries propose patent to protect 'intellectual property' (gmeducation.org)

2009- The FDA publishes 'Guidance for Industry: Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs (non-binding recommendations) (Food and Drug Administration [FDA], 2009b)

By 2011, 88% of corn, 94% of soybeans% and 94% of cotton grown in the US was genetically engineered (Homer, 2011)

2011- USDA grants Aquabounty Technologies nearly \$500, 000 to research methods of rendering GM fish unable to reproduce (USDA, 2011)

2013- FDA to decide if Genetically Engineered (GE) salmon approved for commercial cultivation and human consumption, while countless other GE animals are being developed (Homer, 2011)